A Randomised Controlled Study to Evaluate Efficacy of the Landmark Guided Erector Spinae Plane Block for Postoperative Pain in Percutaneous Nephrolithotomy Surgeries in Kolhapur District in Western Maharashtra

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ABSTRACT

BACKGROUND

Post-operative pain and discomfort is a common side effect of percutaneous nephrolithotomy (PCNL) surgery. The study intended to evaluate the efficacy of landmark guided erector spinae plane block (ESPB) in early post-operative pain relief following (PCNL) surgery.

METHODS

In this randomised prospective, single blind, interventional study, 70 patients aged 20 - 60 years of ASA grade I and II, scheduled for elective percutaneous nephrolithotomy (PCNL) surgery under general anaesthesia were included. Patients were randomly allotted into two groups of 35 each. Group 1 was the control group and received parenteral analgesia according to institutional protocol for postoperative pain relief. Group 2 was the study group and received landmark guided erector spinae plane block (ESPB) with 20 cc of 0.25 % bupivacaine for postoperative pain relief. Post-operatively patients were monitored for pain and Visual Analogue Scale (VAS) score was noted at 2nd, 4th and 6th hr and was maintained below 4 by providing them with additional analgesics if required. Time and doses of analgesics required were recorded.

RESULTS

All the statistical analysis was done using R-Studio 1.2.5001 software. Mann-Whitney-U test was used for quantitative variables of pain score. Proportion test was used for qualitative demographic data and for post-operative analgesics requirement. Both the groups were comparable on demographic variables. The average VAS score at 2nd and 4th hr was significantly lower in the study group than in the control group ($P < 0.05$). The VAS score at 6th hr was comparable in both the groups. The analgesic requirement was significantly lower in study group as compared to the control group.

CONCLUSIONS

The landmark guided ESPB is an effective and simple method to alleviate immediate postoperative pain in PCNL surgeries under general anaesthesia.

KEYWORDS

Erector Spinae Plane Block, Percutaneous Nephrolithotomy Surgery, Postoperative Pain

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BACKGROUND

PCNL is a standard technique for the removal of kidney stones and upper ureteric calculi.[1] In the conventional PCNL procedure first dye is pushed through ureteric catheter in standard way to visualize pelvicalyceal system and then under fluoroscopy control, the affected kidney is accessed by 20 g needle. Afterwards guidewire is inserted through the needle and serial dilatation of tract is done over the guidewire till 24 G. Through the tract the working nephroscope is inserted and stones are fragmented and removed in pieces. At the end of the procedure nephrostomy tube is placed which serves many purposes like immediate tamponade of the bleeding by pressure. It serves as a drainage. Also nephrostomy tract can be utilized as a guide for second look PCNL for staghorn calculi and big stones.[2]

However, one of the major side effects with nephrostomy tube is postoperative pain and discomfort at the nephrostomy site.[3] Many regional techniques are used to control postoperative pain but not a single of these techniques is universally established as standard of care in post-operative pain control. Traditionally used Parenteral opioid analgesics have side effects like nausea, vomiting, respiratory depression, sedation, pruritus, ileus, constipation, urinary retention etc.[4,5] NSAIDs (Nonsteroidal Anti-Inflammatory Drugs) though they serve as a good analgesic in postoperative period, they have issues of renal toxicity and patients posted for PCNL surgeries already have suboptimal renal function. Many surgical modifications are used to overcome this side effect of pain to name few tubeless PCNL, mini-PCNL. But such type of operative options is possible only in limited set of patients.[6,7]

Various local techniques like nephrostomy tube tract infiltration and renal capsule infiltration under fluoroscopy are used with variable and inconsistent result.[5,8] Paravertebral block is one of the best techniques which is utilized for postoperative pain relief for variety of thoracic and abdominal surgical procedures.[9,10] In this block drug is deposited in paravertebral space behind the transverse process of adjacent vertebra and it blocks the emerging spinal nerve roots.

This block is conventionally given either with loss of resistance technique or with ultrasound imaging. When invented this block was used mainly for the pain relief of thoracic procedures like breast cancer surgeries but later on looking at its advantages it is now used for various abdominal procedures also mainly serving as postoperative analgesia. [Diagram: 1] Yet another very novel ESPB, is technically simple regional block which can be used effectively for variety of surgical procedures like Nuss procedure, ventral hernia repairs, thoracotomies and even lumbar fusion to manage their post-operative pain. The first report of the successful use of this procedure was in 2016. In this block, unlike the paravertebral block the local anaesthetic drug is deposited deep to the erector spinae muscles and superficial to the transverse processes of vertebrae. The "erector spinae" comprises a group of muscles including the ilio- costalis, longissimus, and spinalis muscles. They run bilaterally from skull to pelvis and sacrum region and from spinous to transverse processes extending to the ribs. Drug spreads in the longitudinal axis to both caudal and cephalad direction over several levels and blocks the dorsal and ventral rami of emerging spinal nerves of that area. The mechanism of action is not fully understood; some studies suggest that an anterior diffusion of local anaesthetic into the paravertebral space could be one of the explanations, although interfacial spread towards the posterior rami of the spinal nerves is probably the main mechanisms of action. [Diagram: 2] ESPB gives sensory motor block to anterior, posterior, and lateral thoracic and abdominal wall depending upon the level at which the drug is deposited.[11] In this block as we take transverse process as limit of needle insertion, all the time during procedure, we remain superficial to the transverse processes. It is safer in a view of complications like epidural spread of drug and chances of piercing pleura and causing pneumothorax. These complications are mainly encountered in paravertebral block as we go beyond the transverse processes. An ESPB is reported to provide good post-operative analgesia for various procedures like abdominal surgeries, thoracotomies, mastectomies and laparoscopic surgeries.[12,13]

Literature describes continuous ESPB given for pain control in PCNL surgeries, where epidural catheter was placed in ESP under the ultrasonography guidance.[14] Standard ESPB is a USG guided procedure where transducer is placed in a Para median sagittal orientation approximately 2 cm away from midline to visualize transverse process. The needle is inserted in-plane from cranial to caudal direction until the needle tip contacts the transverse process and drug is injected and confirmed by visualization of spread deep to the erector spinae muscle and superficial to the transverse process.

But studies show that the landmark guided technique also has similar drug spread and effect.[15] This study was intended to evaluate the effect of landmark guided erector spinae plane block (ESPB) in immediate postoperative pain in patients undergoing percutaneous nephrolithotomy surgery.

Objectives

1. To compare postoperative pain score at 2nd, 4th and 6th hrs in both the study and control group and to see for statistical significant difference
2. To compare analgesic requirement in both the groups in immediate postoperative period and see for statistical significance difference

METHODS

The prospective study was conducted among 70 patients with age ranging from 20 - 60 years of either gender belonging to ASA status I or II, scheduled to undergo PCNL surgery under general anaesthesia. Study was done from May 2019 to April 2020. Approval for the study was obtained from institutional ethics committee. All the cases underwent thorough preoperative evaluation prior to the surgery and written informed consent was obtained. Patients were also

informed about the intervention ,advantages and side effects and possibility that they may land in any group. Appropriate consent was obtained for the same too. Patients were randomly divided into two groups of 35 each by computer generated random number method.

Group I the control group (N = 35) received parenteral analgesia postoperatively. No intervention done.

Group II the study group (N = 35) received landmark guided ESPB postoperatively as described below.

On the night before surgery all the patients were given tab alprazolam 0.5 mg and tab ranitidine 150 mg orally. Patients were kept nil by mouth since night.

On the day of surgery, patients received 500 cc Ringers lactate (RL) solution and antibiotic just before shifting to theatre. Then patients were shifted to the operation theatre and standard multipara monitor was attached. Patients received uniform endotracheal tube general anaesthesia according to institutional protocol using inj propofol 2 - 3 mg / kg as induction agent, inj vecuronium 0.08 mg / kg as muscle relaxant, inj fentanyl 2 mg / kg as analgesic and isoflurane 1 - 1.2 % as inhalational agent. Surgery was carried out in prone position taking all precautions in standard way. Following the completion of surgery, Group I patients were turned supine for reversal and extubation. Group II patients received landmark guided ESPB in prone position as follows:

ESPB: A point was marked either at T8, T9 vertebral spine level 3 cm lateral towards operating side. Under all aseptic precautions, a 25-gauge spinal needle was inserted perpendicular to the skin in all the planes to contact the transverse process of the vertebra which was found at a depth of 3 - 5 cm from the skin. After contact, the stylet was removed, and 20 cc of 0.25 % bupivacaine was injected following negative aspiration for blood. [Snap 1] The procedure was completed in less than two minutes.

After the block procedure, patients were turned supine and were reversed of neuromuscular block with inj. Neostigmine 0.05 mg / kg and inj glycopyrrolate 0.008 mg / kg. After confirming adequate reversal clinically and with neuromuscular monitor the patients were extubated. Patients of both the groups were given injection tramadol 100 mg in slow iv drip postoperatively. In the recovery room, attending nurse, who was unaware of the study was instructed to keep a record of pain with VAS score at 2nd, 4th, and 6th hrs and to administer parenteral analgesics (paracetamol 1000 mg iv infusion / diclofenac sodium 75 mg) if the VAS was found to be > 4 at any point of time. Attending staff was asked to note the time and the number of doses of analgesics required. The occurrence of any adverse effects were noted.

Statistical Analysis

All the statistical analysis was done using R-Studio 1.2.5001 software. Sample size calculation was done by the package "pwr" in R-Studio 1.2.5001 software. pwr. t. test (d = 0.81, power = 0.90, sig. level = 0.05, type = "two. sample"). For effect size (d = 0.81), significance level 95 %, power 90 %, the sample size is ~ 33 (minimum samples required for each Group). In the given study total of 70 samples were collected. To compare post-operative pain at 2 hr., 4 hr. & 6 hr, we used Mann-Whitney-U Test. The proportion test was used to find out the proportion of analgesic requirement in both the groups.

RESULTS

Figure 3 shows, amongst the overall participants 37 % were females and 63 % were males. The average age of collected sample was 41.85 ± 10.43 yrs. Figure 4 shows almost equal ASA grade wise distribution amongst participants. Table 1 depicts the demographic data where age, sex, ASA grade wise distribution was comparable in both the groups. We can see that more than 60 % were males in both the groups. ASA I and II grades were equally distributed and average age of the participant was around 40 years.

Variable	Group I: Control Group	Group II: Study Group	P-Value
Male	21 (60 %)	23 (65.7 %)	0.8046
Female	14 (40 %)	12 (34.3 %)	0.8046
ASA I	18 (51.4 %)	18 (51.4 %)	1.000
ASA II	17 (48.5 %)	17 (48.5 %)	1.000
Age	41.37 ± 10.43	42.34 ± 10.55	0.6999

Table 1. Demographic Variables in Both the Groups

Time	Group I: VAS	Group II: VAS	P-Value
2nd hr	5.2 ±1.18	3.0 ± 1.49	$1.55e^{-05}$
4th hr	3.3 ± 1.23	2.62 ± 0.97	0.0004
6th hr	2.6 ± 0.55	2.4 ± 0.60	0.1328

Table 2. Analysis of Post-Operative Pain

Control Group I		Study Group II		P-Value
Frequency	%	Frequency	%	$5.77e^{-09}$
33	94.29 %	8	22.86 %	

Table 3. Frequency of Analgesic Requirement

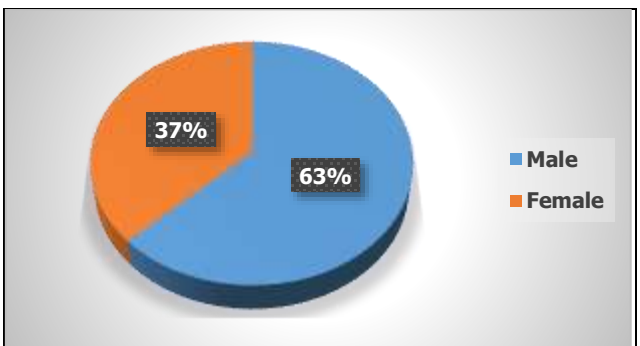

Figure 1. Distribution of Sex in Overall Study

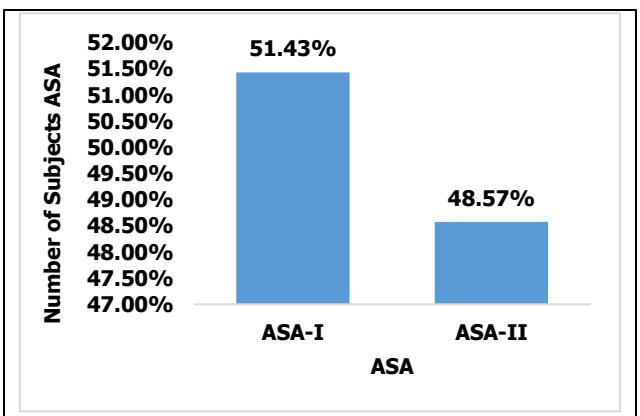

Figure 2. Distribution of ASA Grading in Overall Study

Figure 3. ESPB by Land Mark Technique

From Table 2 which analyses immediate postoperative pain score by VAS, we concluded that at 2nd and 4th hrs post-operatively, group II which is a study group has significantly lower VAS scores as compared to group I, while at 6th hr postoperatively VAS scores were comparable. As our institutional policy we tried to maintain post-operative pain score below 4. As per Table 3 there was significant less analgesic requirement in early post-operative period in Group II i.e. study group as compared to control group. There were no adverse effects noted in any of the groups.

DISCUSSION

Advanced endoscopic renal surgery made it possible to remove big renal stones through small hole made in the kidney which definitely decreases morbidity and mortality as compared to open surgery. Even in these minimally invasive procedures postoperative pain and discomfort remains major problem to tackle as nephrostomy tube placement is associated with postoperative pain. As we all know postoperative pain and patients anxiety about pain have several negative impact on recovery like delayed mobilization, pulmonary complications, more analgesics consumption and its related side effects and all these may prolong patients hospital stay.[4,16,17]

Though large number of anaesthetic techniques are available for post-operative pain relief, one which is quick, effective and safe with minimum side effects is desired. Postoperative analgesia for PCNL surgeries can be provided with systemic opioids analgesia, infiltration of local anaesthetic, paravertebral block and intercostals nerve block.[8,9,10,18] Due to better understanding of pain pathway, pain physiology and availability of various adjuvants acting at various level of pain pathway nowadays multimodal analgesia is utilized intraoperatively for postoperative pain.[19,20] Best results of multimodal analgesia are obtained when it is combined with some form of regional block.[21] In theses plethora of choices, effect of anaesthetic technique on postoperative outcome is not uniform and varied results are obtained, hence the requirement for a flexible, safe, efficient technique has always been the frontline for research. ESPB is a regional field block used effectively for postoperative pain relief in a variety of procedures which include thoracotomies, mastectomies, laparoscopies and abdominal surgeries.[12,13]

ESPB can be done using single shot injection or by threading catheter to give continuous infusion of drug. The mechanism of action is diffusion of injected drug through connective tissue towards spinal nerve roots. Some studies described transforaminal and epidural spread as well. [Fig. 2].

ESPB is usually administered under ultrasound guidance, however land mark guided blocks are equally effective as the drug spread is comparable with the USG guided method and in resources limited set up it can be undertaken.[15] In this study the landmark guided ESPB was compared with conventional parenteral analgesics for post-op pain relief in PCNL surgeries. Somatic pain from the nephrostomy site and Visceral pain originating from the kidneys and ureter are the main sources of pain. Techniques like local infiltration and intercostal nerve block fail to give visceral analgesia which is a major limitation of these techniques. The nerve supply of the kidney is from T10 – L-1 and cutaneous innervations of the incision site is T9 - 11, so a block was administered at the T8 / T9 level. It was observed radiologically that the local anaesthetic drug spread extends three or four levels cranially and caudally. Bupivacaine 0.25 % was used which is a long-acting local anaesthetic and provides long duration of analgesia. The result was encouraging and were comparable with other studies where ESPB was used.[22,23] The patients were observed for 6 hrs postoperatively in recovery area, as during this period, patients experience the highest post-operative pain and after 6 hrs, oral medication may be administered. The procedure was performed postoperatively as it was easy to do so when the patient was still under general anaesthesia and lying prone which saves time. Hence, it is observed that the landmark guided ESPB provides a viable, safe option for immediate post-operative pain control in PCNL surgery and should be utilized regularly in limited resources setup.

Author Eungdon et al used ESPB for postoperative analgesia after PCNL surgery.[14] In their case series they used continuous technique by threading catheter at T8 level under ultrasound and provided analgesia through catheter twice a day for five days. They got very good results in terms of less opioid consumption and good pain control. Author Mukesh Prasad, Rohit K and collegues did randomized control trial where they utilized fluoroscopy guided ESPB technique with very good result, they monitored patients for 24 hrs and used 0.375 % ropivacaine as local anaesthetic agent.[22] Author Mehmat Hamza Abdulla Erdogan and Fethi Akyol published similar randomized control trial where they utilized ultrasonography guided ESPB for postoperative analgesia in PCNL surgeries and got good results as VAS score and analgesic requirement in study group were less than in control group. They observed patients for 24 hrs.[23] We came across published case series by Resnick Andrew et al. where they utilized ESPB by inserting catheter at T7 under ultrasonography in preoperative period and gave 30 ml of 0.25 % bupivacaine as bolus dose and postoperatively patients received one more 10 cc bolus. They reported very low VAS score and no additional analgesic requirement in immediate postoperative period.[24] Swati Bist and Sampreeta Reddy published case series of ultrasound guided pre-emptive ESPB as a part of enhanced recovery after surgery (ERAS) in abdominal surgeries where they carried out pre-emptive ESPB in one PCNL case with good result. They observed the patients for two days.[25] So all the case series

and studies done on ESPB for postoperative analgesia in PCNL surgery got similar results as ours.

CONCLUSIONS

Landmark guided ESPB is quick, safe and effective way to control early post-operative pain of PCNL surgeries.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
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